

Chronic Mechanical Neck Pain in Adults Treated by Manual Therapy: A Systematic Review of Change Scores in Randomized Controlled Trials of a Single Session

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Neck pain is a very common problem, second only to low back pain in its frequency in the general population¹⁻⁴ and in musculoskeletal practice⁵. Approximately 15% of females and 10% of males suffer with chronic neck pain at any one time⁶⁻⁸. Chronic neck pain produces a high level of morbidity by affecting occupational and avocational activities of daily living and by affecting quality of life⁹⁻¹².

Manual therapies are commonly used in the treatment of chronic neck pain, and there are numerous systematic

reviews of the treatment of neck pain by manual therapy¹³⁻³⁹. In a recent report⁴⁰, we reviewed all studies of manual therapies for chronic neck pain, focusing on the change scores obtained after courses of treatments of various manual therapies. However, the issue of change scores in studies of single sessions of these treatments has received little attention.

The importance of single-session trials of a treatment can be viewed in two ways. First, the trials provide a form of *proof of principle* in that the studies indicate whether a single dose of the treat-

ment achieves an appropriate level of the intended outcome. Indeed, dose-dependence can be directly evaluated in these types of studies. Conversely, such studies can provide data on the utility of potential outcome measures for subsequent studies. Second, as most treatments are provided in a series or regimen, these studies provide clinicians and researchers with an indication of the expected outcome on each session of the treatment, at least at the outset of the treatment program. This indication must be tempered with the notion that the cumulative effects of several sessions may not accumulate in a linear fashion, and that the within-session changes may vary during the course of the treatment.

Recent interest in single session changes has grown among researchers. Tseng et al⁴¹ developed a preliminary prediction rule for cervical manipulation in a group of mostly chronic neck pain sufferers. Using the criterion of either 50% pain relief, 4 out of 7 on a global rating of change, or the rating of "very satisfied" with outcome to determine "responders," 60% of their sample achieved this level after a single session. A prediction rule⁴¹ consisting of seven baseline criteria was developed. Subjects with 3 out of 7 criteria had a 74% chance of being a responder; subjects with 5-6 criteria were 100% likely to respond. Tuttle et al^{42,43} investigated the degree to which within-session changes in the first one⁴² or two⁴³ treatments predict responses in subsequent treatments. They found a positive corre-

ABSTRACT: We report a systematic analysis of group change scores of subjects with chronic neck pain not due to whiplash and without headache or arm pain, in randomized clinical trials of a single session of manual therapy. A comprehensive literature search of clinical trials of chronic neck pain treated with manual therapies up to December 2006 was conducted. Trials that scored above 60% on the PEDro Scale were included. Change scores were analyzed for absolute, percentage change and effect size (ES) whenever possible. Nine trials were identified: 6 for spinal manipulation, 4 for spinal mobilization or non-manipulative manual therapy (2 overlapping trials), and 1 trial using ischemic compression. No trials were identified for massage therapy or manual traction. Four manipulation trials (five groups) reported mean immediate changes in 100-mm VAS of -18.94 (9.28) mm. ES for these changes ranged from .33 to 2.3. Two mobilization trials reported immediate VAS changes of -11.5 and -4 mm (ES of .36 and .22, respectively); one trial reported no difference in immediate pain scores versus sham mobilization. The ischemic compression study showed statistically significant immediate decreases in 100-mm pain VAS (average = -14.6 mm). There is moderate-to-high quality evidence that immediate clinically important improvements are obtained from a single session of spinal manipulation. The evidence for mobilization is less substantial, with fewer studies reporting smaller immediate changes. There is insufficient evidence for ischemic compression to draw conclusions. There is no evidence for a single session of massage or manual traction for chronic neck pain.

KEYWORDS: Clinical Trials, Manipulation, Manual Therapy, Mobilization, Manual, Neck Pain.

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lation at one week for only range of motion changes vs. changes on pain scores.

To date, there has been no summary of the magnitudes of change in pain scores reported in the clinical trials of manual therapies for chronic neck pain. In the present report, we focus our review on change in pain scores in those clinical trials of a single session of manual therapies for adults with chronic neck pain (without headache, whiplash, or arm pain).

Methods

Search Strategy

A comprehensive literature search was performed in MEDLINE and CINAHL using the strategy illustrated in Table 1. Targeted text word searches were conducted in AMED, MANTIS, and Index to Chiropractic Literature (ICL) using the terms *neck pain*, *randomized clinical trial*, *manual therapy*, *manipulation*, and *mobilization*. Several recent systematic reviews^{18,36-39} were searched directly. Hand searches were also conducted of reference lists. Searches were conducted up to late 2006.

Inclusion Criteria

The following inclusion criteria were then applied: *RCT*: The study design had to be a randomized clinical trial in which at least one treatment group of adults ages 18–50 was provided with a course of one of the manual therapies (as defined below) for chronic mechanical neck pain. *Chronicity*: Chronic neck pain has been variously defined as to its duration. Some authors require at least three months of continuous symptoms while, for others, *chronicity* can develop after only one month of symptoms⁴⁴. We defined chronic neck pain as being of a minimum of eight weeks duration. *Neck pain*: This review included only studies with subjects with neck pain without arm pain or headache and not due to whiplash injury. *Treatment*: For this review, we employed the separate therapy categories of manipulation, mobilization, manual traction, massage, and

pressure techniques. *Outcome*: The primary outcome was *pain* (function-related outcomes such as measures of self-reported disability or measures of ranges of motion were also included if a pain-related outcome was present).

Quality Scoring

Once selected, the method of each study was scored using the PEDro Scale⁴⁵. This scale has good reliability⁴⁶ and was selected for its appropriateness to the task of evaluating studies of a single intervention⁴⁶. The PEDro Scale provides a score out of 10; we identified 6/10 as the cut-off for acceptable quality. Two assessors (HV and BKH) scored studies separately, and disagreements were resolved by consensus. Evidence tables were compiled from extracted data by the primary author and a research assistant. Data were obtained only from the published works and not from follow-up with authors.

Analyses

When continuous data were reported, as means and standard deviation (SD) for baseline and outcome intervals, absolute and relative changes were calculated. Intra-group effect sizes were calculated according to the method of Cohen^{47,48}. Where median scores were reported, the confidence intervals were used to calculate proxy standard deviations and the median was treated as the mean. Where only change scores were reported (as opposed to both pre- and post-intervention scores), the effect size was not calculated. Where possible, change scores were averaged (mean [95% Confidence Interval]). Given that this is a secondary analysis, no further analysis such as weighting of effects was undertaken.

Results

The MEDLINE and CINAHL searches generated 799 citations (Table 1). Table 2 shows the results of the application of the inclusion criteria to this search.

Eight trials were identified by this process. The AMED, MANTIS, and ICL searches generated no additional studies. Hand searches identified one addi-

tional trial⁴⁹. Nine trials were ultimately selected for inclusion⁴⁹⁻⁵⁷, six of which involved spinal manipulation, four of which involved spinal mobilization or non-manipulative manual therapy (2 trials overlapped with 2 manipulation trials), and one that involved manual trigger point therapy. No trials included massage therapy or manual traction of the neck.

The PEDro scores for the nine included studies are shown in Table 3. All nine studies scored at least 6 out of 10. The most frequently deficient items were *concealment of allocation*, *blinding of all subjects*, and *blinding of all therapists*.

A total of 223 subjects with chronic neck pain only were included in the manipulation studies (Table 4). Baseline pain levels were obtained from 3 studies⁵⁰⁻⁵², ranging from 37 to 57 mm/100. Four manipulation studies (five groups)⁵⁰⁻⁵³ were judged to be sufficiently similar and homogeneous to permit summarizing of their change scores. The mean immediate change in these four trials in a 100-mm VAS was -18.94 [7.42,30.16] mm. A medium effect size (ES) for immediate change in 100-mm VAS was obtained in two studies at .33⁵¹ and .52⁵⁰ while one study reported a large ES at 2.3⁵². One study also reported mean change scores at 5 hours post-manipulation of -10.4 mm⁵³. One study reported change scores only at 3 weeks post-manipulation, obtaining a mean of 18 mm improvement⁵⁴. The other study reported on immediate changes in paraspinal tenderness scores, obtaining an average increase of 45% post-manipulation⁵⁵. Mild, temporary pain-related adverse effects were reported in 6–17% of subjects in three studies^{50,53,54}. No major adverse reactions (defined as any reaction requiring additional medical intervention at any time) were reported in any of these studies.

A total of 115 subjects were included in 4 studies employing a spinal mobilization group. Baseline pain levels were obtained from two trials: 31 and 55/100 mm^{50,52}. Two trials reported immediate changes in a 100-mm VAS of -11.5 and -4 mm, respectively^{50,52}. These changes amounted to an ES of .36⁵⁰ and .22⁵², respectively. One trial reported no difference in pain change scores of the

TABLE 1. Search Strategy: MEDLINE and CINAHL; Results: 799.

| | |
|-----|-------------------------------------------------------------------------------|
| S66 | (S64 and S62 and S61) = 799 |
| S65 | (S64 and S62 and S61) |
| S64 | (S63 or S53) |
| S63 | (randomis* or randomiz*) |
| S62 | (S60 or S59 or S54) |
| S61 | (S58 or S57 or S32) |
| S60 | (MH "Manipulation, Orthopedic") |
| S59 | (MH "Chiropractic") |
| S58 | (MH "Myofascial Pain Syndromes+") |
| S57 | (mh neck and mh pain) |
| S56 | (S54 and S53 and S32) |
| S55 | (S54 and S53 and S32) |
| S54 | (S41 or S40 or S39 or S38 or S37 or S36 or S35 or S34 or S33) |
| S53 | (S52 or S51 or S50 or S49 or S48 or S47 or S46 or S45 or S44 or S43 or S42) |
| S52 | ti placebo* |
| S51 | (MH "Placebos") |
| S50 | (MH "Placebo Effect") |
| S49 | (MH "Research Design+") |
| S48 | (MH "Clinical Trials+") |
| S47 | (MH "Epidemiologic Research Design+") |
| S46 | PT "Randomized Controlled Trial" |
| S45 | ((MH "Random Allocation") or (MH "Randomized Controlled Trials")) |
| S44 | PT "Clinical Trial" |
| S43 | PT "Controlled Clinical Trial" |
| S42 | (MH "Controlled Clinical Trial [Publication Type]") |
| S41 | (ab chiropract* or naturopath* or homeopath* or acupunctur*) |
| S40 | (ti chiropract* or naturopath* or homeopath* or acupunctur*) |
| S39 | osteopath* |
| S38 | (MH "Osteopathic Medicine") |
| S37 | (physical N1 therapy or physiotherapy) |
| S36 | (MH "Physical Therapy Modalities+") |
| S35 | holistic |
| S34 | (MH "Holistic Health") |
| S33 | (MH "Complementary Therapies+") |
| S32 | (S31 or S30 or S29) |
| S31 | (MH "Cervical Vertebrae+") |
| S30 | neck N1 pain |
| S29 | (MH "Neck Pain") |
| S28 | (S26 and S25 and S4) |
| S27 | (S26 and S25 and S4) |
| S26 | (S13 or S12 or S11 or S10 or S9 or S8 or S7 or S6 or S5) |
| S25 | (S24 or S23 or S22 or S21 or S20 or S19 or S18 or S17 or S16 or S15 or S14) |
| S24 | ti placebo* |
| S23 | (MH "Placebos") |
| S22 | (MH "Placebo Effect") |
| S21 | (MH "Research Design+") |
| S20 | (MH "Clinical Trials+") |
| S19 | (MH "Epidemiologic Research Design+") |
| S18 | PT "Randomized Controlled Trial" |
| S17 | ((MH "Random Allocation") or (MH "Randomized Controlled Trials")) |
| S16 | PT "Clinical Trial" |
| S15 | PT "Controlled Clinical Trial" |
| S14 | (MH "Controlled Clinical Trial [Publication Type]") |
| S13 | (ab chiropract* or naturopath* or homeopath* or acupunctur*) |
| S12 | (ti chiropract* or naturopath* or homeopath* or acupunctur*) |
| S11 | osteopath* |
| S10 | (MH "Osteopathic Medicine") |
| S9 | (physical N1 therapy or physiotherapy) |
| S8 | (MH "Physical Therapy Modalities+") |
| S7 | holistic |
| S6 | (MH "Holistic Health") |
| S5 | (MH "Complementary Therapies+") |
| S4 | (S3 or S2 or S1) |
| S3 | (MH "Cervical Vertebrae+") |
| S2 | neck N1 pain |
| S1 | (MH "Neck Pain") |

TABLE 2. Tabulation of exclusion criteria application.

| Exclusion Criterion | Number Rejected | Total (N = 799) + (1) Hand search |
|-----------------------------------------------------------------|-----------------|-----------------------------------|
| 1. Randomized clinical trial of a manual therapy | 684 | 116 |
| 2. Cervical spine | 12 | 104 |
| 3. Only neck pain?; not arm pain?; not headache?; not whiplash? | 42 | 62 |
| 4. Single session vs. course of therapy | 45 | 17 |
| 5. Chronic | 3 | 14 |
| 6. Included only a non-pain measurement | 5 | 9 |
| 7. Accepted manuscripts | | 9 |

mobilization group as compared to the group receiving sham mobilization⁵⁶. Two trials reported on immediate changes in local pressure pain thresholds, obtaining 19%⁵⁷ and 22.5%⁵⁶ increases, respectively. One study reported mild, temporary pain-related adverse effects in 6% of subjects⁵⁰. No major adverse reactions were reported in any of these studies.

For the single trial of trigger point therapy⁵⁷ (Table 5), 6 ischemic compression protocols were investigated, with several showing statistically significant increases in local pressure pain threshold (average = 26%) and all showing a statistically significant immediate decrease in 100-mm VAS (average = -14.6 mm).

Discussion

To our knowledge, we are the first to report on the within-group changes of pain scores from clinical trials of a single session of a manual therapy for chronic neck pain in adults. In their recent review, Bronfort et al¹⁸ did not address this issue directly and included only the study by Sloop et al⁵⁴. As that study acquired its outcomes three weeks after the intervention, they likely regarded it as a

TABLE 3. PEDro scores for the accepted manuscripts.

| PEDro item/Study | 1 Eligibility Total | 2 Random Allocation | 3 Allocation Concealed | 4 Similar At Baseline | 5 Subjects Blinded | 6 Therapists Blinded | 7 Assessors Blinded | 8 Outcome Measure | 9 Intention "To Treat" | 10 Comparisons Reported | 11 Point Measurements |
|-------------------------------------|---------------------------|---------------------------|------------------------------|-----------------------------|--------------------------|----------------------------|---------------------------|-------------------------|------------------------------|-------------------------------|-----------------------------|
| Sloop et al ⁵⁴ | 8 | + | + | + | -- | + | -- | + | + | + | ++ |
| Vernon et al ⁵⁵ | 6 | + | + | -- | -- | -- | -- | + | + | + | ++ |
| Cassidy et al ⁵⁰ | 7 | + | + | -- | + | -- | -- | + | + | + | ++ |
| Yurkiw & Mior ⁵¹ | 7 | + | + | -- | + | -- | -- | + | + | + | ++ |
| Hanten et al ⁴⁹ | 6 | + | + | -- | + | -- | -- | + | + | -- | ++ |
| Sterling et al ⁵⁶ | 7 | + | + | -- | -- | + | -- | + | + | + | ++ |
| Hou et al ⁵⁷ | 6 | + | + | -- | -- | -- | -- | + | + | + | ++ |
| Haas et al ⁵³ | 10 | + | + | + | + | + | + | + | + | + | ++ |
| Martinez-Segura et al ⁵² | 7 | + | + | -- | + | -- | -- | + | + | + | ++ |

Important deficiencies: 3 – allocation concealed, 5 – blinding of all subjects, 6 – blinding of all therapists.

longitudinal study, even though only a single intervention was provided. Bronfort et al¹⁸ provided no summary of evidence nor any clinical recommendations regarding single-session studies.

In recent Cochrane reviews, Gross et al³⁶⁻³⁸ included 4 single-session studies, three of which^{50,54,55} were included in this review. Those authors also included the trial by Howe et al⁵⁸; however, this study did not include a group receiving only manipulation, thus we excluded it from our review. Gross et al³⁶⁻³⁸ conducted a pooled analysis of Vernon et al⁵⁵ and Sloop et al⁵⁴, given that they were *clinically comparable and not statistically heterogeneous*. Outcome measures were pooled despite the fact that Vernon et al⁵⁵ obtained only pressure algometry readings, not pain scores, at 5 minutes post-intervention and included a mobilization group, while Sloop et al⁵⁴ obtained pain outcome only at 3 weeks post-intervention. Despite these considerable problems, Gross et al³⁶⁻³⁸ concluded from their analysis that “when compared to a control (other treatments deemed to be ineffective), there was moderate evidence that single sessions [of manipulation or mobilization] did not result in short-term pain relief [pooled SMD -0.51 (95% CI: -1.10 to 0.07)]” for acute, sub-acute, or chronic neck pain.

Our review differs from these two previous reviews in a number of ways. First, our primary objective was an anal-

ysis of the within-group, as opposed to between-group change scores in groups having received a single session of the treatments of interest. Second, our interest was exclusively in studies of a single session. Third, the scope of our review was larger, involving massage, pressure therapies, and manual traction, leading to the inclusion of additional studies such as Yurkiw et al⁵¹ for manipulation and Sterling et al⁵⁶ and Hanten et al⁴⁹ for mobilization (the more recent studies of Haas et al⁵³ and Martinez-Segura et al⁵² were not available at the time for either the reviews of Bronfort et al¹⁸ or Gross et al³⁶⁻³⁸). Fourth, more sophisticated analyses such as pooling of effects were not conducted. Lastly, our review remained within the boundaries of studies of chronic neck pain treated with one or more forms of manual therapy.

The subjects included in these studies were relatively homogeneous, not only because of the application of our selection criteria but also because of the similarity of baseline pain severity. In addition, these studies appeared to be similar in regard to the types of treatments employed: manipulations were delivered as single-thrust procedures while mobilizations appeared to be relatively similar in application. Finally, most studies employed the same outcome measure of pain severity on a 100 mm scale (see below re: Farrar et al⁵⁹), although a few reported on pressure pain thresholds measured by algometry.

Given these clinical and statistical similarities, and given the sufficiently high quality of the studies reviewed, we felt that it was tenable to summarize the results of the 4 manipulation studies that reported pre- and post-intervention VAS scores and then derive a mean change score. This was not possible for the mobilization studies.

The question then arises as to how to interpret our findings. In a previous review⁶⁰, we referred to the work of Farrar et al⁵⁹ in establishing that the minimum clinically important difference in pain severity scores on the VAS as registered by a large variety of patients with chronic pain is 20 mm. This applies to participants in studies of courses of various treatments for their pain, courses extending over days and weeks. In the case of the present review, outcomes were obtained immediately following the interventions. We could not identify any study that provided a similar reference frame for studies of a single-session of treatment for chronic pain patients.

We did identify one study concerning *single-session changes* in acute pain patients. Bird and Dickson⁶¹ studied emergency-room pain patients and reported that with initial pain VAS scores between 34–66, the minimal clinically important in-session difference in pain score was 17 [95% CI:13, 21] mm; for achieving the outcome of *a lot less pain*, the mean score was 33 [24, 42] mm. The baseline pain scores of the 4 pre- and

TABLE 4. Evidence table for RCTs of a single intervention of a manual therapy: Manipulation.

| Study/ Year | Experimental Group (Sample Size) | Comparative Treatment (Sample Size) | Outcome Time Intervals | Results: Pain and Function | Reported Adverse Reactions |
|-----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Sloop et al. 1982 ⁵⁴ | Single treatment of manipulation + valium (n=21) | Single treatment of valium only (n=18) (Non-responders after 3 weeks given a manipulation) | Initially = 3 weeks Follow up: 12 weeks | <u>Pain</u> 3 weeks: Pain improvement (NAS 0–100) 12 weeks: Pain improvement (Did treatment help?) Single treatment of manipulation + valium 3 weeks: –18 (31) 12 weeks: 7/9 + (78%) Single treatment of Valium: 3 weeks: –5 (32) 12 weeks: 2/6 + (33%) NS between groups at 3 weeks and 12 weeks. None of the non-responders at 3 weeks who were given a manipulation responded well <u>Function</u> None reported | Two subjects had “new discomfort” in neck followed by improvement in their chronic neck pain Valium: Two subjects had superficial phlebitis and recovered |
| Vernon et al. 1990 ⁵⁵ | Single session intervention of Manipulation (n=5) | Single session intervention of Mobilization (n=4) | Immediately post treatment | <u>Pain</u> Average percent improvement in 4 local tender points on pressure algometry Manipulation improvement: 45% (p<0.01) Mobilization improvement: 0% <u>Function</u> None reported | None reported |
| Cassidy et al. 1992 ⁵⁰ | Single session intervention of Manipulation (n=52) | Single session intervention of Mobilization (n=48) | Immediately post treatment | <u>Pain</u> (NAS 0–100) Single session of Manipulation Baseline NAS: 37.7 (25.9) Post Treatment NAS: 20.4 (21.2)* ES = .52 Single session of Mobilization Baseline NAS: 31.0 (19.9) Post Treatment NAS: 20.5 (21.0) ES = .36 * initially reported as significant difference (p=.05). 1993 letter retracted this difference. <u>Function</u> None reported | 6% in each group (3 per group) reported more pain after the procedure |
| Yurkiw & Mior. 1996 ⁵¹ | First group: Single session intervention of Manipulation (n=7) Second Group: Single session of Manually- assisted Instrument Manipulation (n=7) | None | Immediately post treatment | <u>Pain</u> (NAS 0–100) First group: Manipulation Baseline NAS: 32.9 (25.8) Post Treatment NAS: 21.9 (21.4) ES = .33 Second Group: Manually-assisted instrument manipulation Baseline NAS: 32.8 (17.9) Post Treatment NAS: 20.4 (18.4) ES = .48 NS between groups <u>Function</u> None reported | None reported |

TABLE 4. (Continued)

| Study/ Year | Experimental Group (Sample Size) | Comparative Treatment (Sample Size) | Outcome Time Intervals | Results: Pain and Function | Reported Adverse Reactions |
|--------------------------------------------------|---------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Haas et al. 2003 ⁵³ | Single session Manipulation (SMT-ep) based on end-play findings (n=52) | Single Manipulation (SMT-comp) not based on end-play findings (computer selected) (n=52) | Immediately after treatment and 5 hours later | <p><u>Pain</u> (change scores: 0–100) (compared to baseline)</p> <p>Single session SMT-ep Immediately after treatment: –15.7 mm (18), $p<0.01$ 5 Hours later: –10.4 (19.2), $p=.001$</p> <p>Single session SMT-comp Immediately after treatment: –15.7 (20.4), $p=.000$ 5 Hours later : –11.7 (19.0), $p=.000$</p> <p>NS between groups</p> <p><u>Stiffness</u> (change scores: 0–100)</p> <p>Single session SMT-ep Immediately after treatment:– 19.3 (19.2), $p=.000$ 5 Hours later: –10.8 (19.0), $p=.000$</p> <p>Single session SMT-comp Immediately after treatment: –20.3 (18.1), $p=.000$ 5 Hours later: –14.5 (19.1), $p=.000$</p> <p>NS between groups</p> <p><u>Function</u> None reported</p> | 17% of both groups had mild exacerbation of pain immediately |
| Martinez- Segura et al. 2006 ⁵² | Single session of Manipulation (n = 34) | Single session of Mobilization (n = 37) | Immediately post treatment | <p><u>Pain</u> (NAS 0–100)</p> <p>Single session of Manipulation Baseline: 57 (15) Immediately post treatment: 22 (15) ES = 2.3</p> <p>Single session of Mobilization Baseline: 55 (1.7) Immediately post treatment: 51 (19) ES = .22</p> <p><u>Function</u> None reported</p> | None reported |

SMT = spinal manipulative therapy; NS = non-significant; PPT = pressure pain threshold; NAS = numeric analogue scale; ES = effect size; SMT-ep = SMT based on end-play findings; SMT-comp = SMT based on computer-selected site.

TABLE 5. Evidence for RCTs of a single intervention of a manual therapy: Mobilization and manual trigger point therapy.

| Study/ Year | Experimental Group (Sample Size) | Comparative Treatment (Sample Size) | Outcome Time Intervals | Results: Pain and Function | Reported Adverse Reactions |
|------------------------------------------|------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| Cassidy et al. 1992 ⁵⁰ | Single treatment of Mobilization (n=48) | Single treatment of Manipulation (n=52) | Immediately post treatment | <p><u>Pain</u> (NAS 0–100)</p> <p>Single treatment of Mobilization Baseline: 31.0 (19.9) Immediate post treatment: 20.5 (21.0) ES = .36</p> <p>Single treatment of Manipulation Baseline: 37.7 (25.9) Immediate post treatment: 20.4 (21.2)* ES = .52</p> <p>*initially reported as significant difference (p=.05). 1993 letter retracted this difference.</p> <p><u>Function</u> None reported</p> | 6% in each group (3 per group) reported more pain after the procedure |
| Hunten et al. 1997 ⁴⁹ | Single 5 minute session of occipital release Mobilization (n=20) | Single 5 minute session of head retraction exercise (n=20) Control Group (n=20) | Immediately post treatment | <p><u>Pain</u> Pressure pain thresholds (kg/sq.cm)</p> <p>Single treatment of Mobilization Baseline: 2.1 (1) Immediate post treatment: 2.5 (1.1)</p> <p>Head retraction exercise Baseline: 2.2 (1) Immediate post treatment: 2.8 (1.3)</p> <p>Control Group Baseline: 2.2 (1.2) Immediate post treatment: 2.6 (1.5)</p> <p>NS between time and group</p> <p><u>Function</u> None reported</p> | None reported |
| Sterling et al. 2001 ⁵⁶ | Single session of Mobilization (n=10) | Single session of Sham Mobilization (n=10) Single session for control (n=10) Each subject underwent all three treatments | Immediately post treatment | <p><u>Pain</u> (at rest 0–100 VAS)</p> <p>Baseline and post treatment (sd) not reported Single session of mobilization > Control p=.04 NS between Single session of Mobilization and Sham Mobilization</p> <p><u>Pain</u> (at end of rotation) No differences between groups</p> <p><u>Tender points on pressure algometry</u> Single session of Mobilization > Sham Mobilization and Control p = .004 Mean increase in Single session of Mobilization group for pressure algometry = 22.55%</p> <p><u>Function</u> None reported</p> | None Reported |

TABLE 5. (Continued)

| Study/ Year | Experimental Group (Sample Size) | Comparative Treatment (Sample Size) | Outcome Time Intervals | Results: Pain and Function | Reported Adverse Reactions |
|-------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| Martinez-Segura et al. 2006 ⁵² | Single treatment of Mobilization (n=37) | Single session of Manipulation (n=34) | Immediately post treatment | <p><u>Pain</u> (NAS 0–100)</p> <p>Single session of Mobilization Baseline: 55 (1.7) Immediately post treatment: 51 (19) ES = 2.3</p> <p><u>Function</u> None reported</p> | None reported |
| Hou et al. 2002 ⁵⁷ | <p>A. <u>Study 1</u> Ischemic compression: 1. P1T1 (n=8, 14 TP's) 2. P1T2 (n=8, 14 TP's) 3. P1T3 (n=8, 14 TP's) 4. P2T1 (n=8, 14 TP's) 5. P2T2 (n=8, 14 TP's) 6. P2T3 (n=8, 14 TP's) P1=pain threshold pressure level P2=average of pain threshold + pain tolerance T1 = 30 sec T2 = 60 sec T3 = 90 sec</p> <p>B. Study 2 Therapeutics:</p> <p>Treatment 1: Heat + stretching Treatment 2: 1 + ischemic compression Treatment 3: 2 + TENS Treatment 4: 1+ spray and stretch Treatment 5: 4 + TENS Treatment 6: 1 + IFC + myofascial release</p> | None | Immediately post treatment | <p><u>Pressure Pain Threshold</u> Baseline: P1T1: 4.0 (1.0) P1T2: 3.0 (.61) P1T3: 3.2 (.86) P2T1: 3.1 (.82) P2T2: 3.1 (.7) P2T3: 3.3 (.54)</p> <p>Immediately Post Treatment: P1T1: 4.0 (.94) P1T2: 3.2 (.67) P1T3: 4.0 (1.2)* P2T1: 3.8 (.92)* P2T2: 3.8 (.81)* P2T3: 4.4 (.87)*</p> <p>* p<.05</p> <p><u>Pain VAS</u> (0–10) Baseline: Treatment 1: 5.2 (.98) Treatment 2: 5.6 (1.3) Treatment 3: 5.2 (1.7) Treatment 4: 5.2 (1.8) Treatment 4: 5.2 (1.8) Treatment 5: 5.5 (1.3) Treatment 6: 5.6 (1.5)</p> <p>Immediately Post Treatment: Treatment 1: 4.6 (.85)* Treatment 3: 3.4 (1.1)* Treatment 4: 3.7 (1.3)* Treatment 5: 3.5 (1.0)* Treatment 6: 3.6 (1.0)*</p> <p>* p<.05</p> <p>Groups 4, 5 & 6 > 1, 2 & 3 (p<.05) for PPT and for pain VAS</p> <p><u>Function</u> None reported</p> | None Reported |

NS = non-significant; tx = treatment; man = manually performed manipulation; inst = instrument-assisted manipulation; SMT-ep = SMT based on end-plate findings; SMT-comp = SMT based on computer-selected site; sd = standard deviation; PPT = pressure pain threshold; VAS = visual analogue scale; NAS = numeric analogue scale; NS = non-significant.

post-manipulation studies in our review⁵⁰⁻⁵³ lie in the same range as those of Bird and Dickson. Their level of minimal clinically important difference (17 mm) in a single emergency-room treatment session is similar to the average level of change (-18.94 [7.42,30.16] mm) that we found in these 4 studies. With Farrar et al⁵⁹, Vernon et al⁶⁰, and Bird and Dickson⁶¹ as references, we advocate that the mean change in pain score of -18.9 [7.42,30.16] mm immediately after a single manipulation in 4 similar studies⁵⁰⁻⁵³ represents a clinically important finding.

The findings with respect to manual pressure techniques and mobilization permit neither summarization nor simple interpretation. We believe that the results of the manual pressure techniques and mobilization studies are best left in the studies' descriptive mode for use by future clinical trial planners. The results provide some indication of the magnitudes of clinical change that can be expected in a single session of the various types of mobilizations included in these studies.

With respect to our approach to within-group analysis, it could be asked if it is appropriate to conduct such analyses from a set of published RCTs. Only one of the manipulation trials⁵⁴ included a comparison between a form of manual therapy and a placebo control procedure (anamnesic valium only). Only one of the mobilization trials included a sham procedure⁵⁶. The remaining majority of trials are more properly seen as randomized comparative trials in which none of the subjects in these trials were blinded as to the form of treatment they received. Two studies compared manipulation to mobilization^{50,52} whereas two studies compared two different modes of manipulation^{51,53}.

We maintain that once the inter-group outcomes of manual therapy trials have been analyzed in standard systematic reviews^{18,36-38}, it then becomes appropriate to assess the magnitudes of change within each treatment group randomized to receive the therapy of interest and, if possible, to summarize the results among studies. In fact, several

studies in this review only reported change scores⁵³⁻⁵⁵. After hypothesis testing has been conducted, it is reasonable to assess these scores individually for clinical relevance. Our sub-group analysis only extends this exercise to the collective body of trials in this area of interest.

Limitations

Our study has limitations. The major limitation was the lack of high-quality RCTs that included clearly identifiable patient groups undergoing single-session manual treatments. Consequently, our review included only 4 trials of spinal manipulative therapy, only 4 trials of spinal mobilization and only 1 trial of trigger point therapy. No trials were identified for massage therapy or traction. In terms of quality, only one manipulation trial and one mobilization trial included a placebo control or sham group.

Our quality assessment suggests that weaknesses were associated with concealment of allocation and in blinding of subjects and therapists. In addition, most studies failed to report the presence or absence of adverse reactions. Only Sloop et al⁵⁴ and Haas et al⁵³ incorporated a double-blind design, while in none of the other studies were either therapists or subjects blinded to the interventions. This is a common problem in clinical trials of manual therapies⁴⁰. There is an urgent need for a reliable sham procedure for future trials of these manual therapies, whether with single or multiple intervention sessions.

In addition, not all trials in this review used pain severity as measured on a 100-mm scale as the main outcome. Some used pressure algometry or a mix of outcomes. There were also variations in post-measurement for the main outcome measure. Some outcomes were measured immediately, others at 5 hours or 3 weeks after the single manual therapy intervention. Calculations such as effect sizes and comparisons of manual therapies were made more complicated as a result of differences in the outcomes measured, data reported (continuous

versus ordinal; means or median scores; varied measures of variability; change scores versus pre- and post-intervention scores) and the timing of measurements (post-treatment).

Another problem was the differences in baseline pain severity scores for different trials, which made it difficult to pool patient treatment groups for the various manual therapies. In terms of inclusion criteria, chronic neck pain varied from one to three months depending on the trial.

Finally, as discussed previously, the minimal clinically important difference (MCID) in pain severity immediately following a single session of manual therapy has not been defined for manual therapies. For this review, work by Bird and Dickson⁶¹ in emergency-room pain patients was used. More studies are needed to identify the MCID for manual therapies after a single session.

Conclusion

Investigators have studied the effects of a single session of a variety of manual therapies for chronic neck pain by reporting on changes in subjective pain, local tenderness, and regional ranges of motion. The largest number of studies has involved spinal manipulation. There is moderate- to high-quality evidence that subjects with chronic neck pain not due to whiplash and without arm pain and headaches who are randomized to receive a single session of spinal manipulation demonstrate immediate improvements which, in comparison to published benchmarks, could be considered clinically important. A minority of subjects have reported brief, mild pain-related side effects following this intervention. The evidence for mobilization is less substantial, with fewer studies reporting smaller immediate changes. The evidence for manual trigger point therapy is insufficient to draw conclusions. There is no evidence concerning the effects of a single session of massage or manual traction for chronic neck pain. Further high-quality studies are recommended to better determine the magnitudes of change in clinically important

measures after a single session of any of the variety of manual therapies.

REFERENCES

- Nachemson A, Waddell G, Norlund AI. Epidemiology of neck and back pain. In: *Neck and Back Pain: The Scientific Evidence of Causes, Diagnosis and Treatment*. Nachemson A, Jonsson E, eds. Philadelphia, PA: Lippincott Williams and Wilkins, 2000.
- Wolsko PM, Eisenberg DM, Davis RB, Kessler R, Phillips RS. Patterns and perceptions of care for treatment of back and neck pain: Results of a national survey. *Spine* 2003;28:292–298.
- Webb R, Brammah T, Lunt M, Unwin M, Allison T, Symmons D. Prevalence and predictors of intense, chronic and disabling neck and back pain in the UK general population. *Spine* 2003;28:1195–1202.
- Cote P, Cassidy JD, Carroll L. The Saskatchewan Health and Back Pain Survey: The prevalence of neck pain and related disability. *Spine* 1998;23:1689–1698.
- Waalén DP, White TP, Waalen JK. Demographic and clinical characteristics of chiropractic patients: A five-year study of patients treated at the Canadian Memorial Chiropractic College. *J Can Chiro Assoc* 1994;38:75–82.
- Guez M, Hildingsson C, Nilsson M, Toolanen G. The prevalence of neck pain: A population-based study from northern Sweden. *Acta Orthop Scand* 2002;73:455–459.
- Makela M, Heliövaara M, Sievers K, Impivaara O, Knecht P, Aromaa A. Prevalence, determinants and consequences of chronic neck pain in Finland. *Am J Epidemiol* 1991;134:1356–1367.
- Bovim G, Schrader H, Sand T. Neck pain in the general population. *Spine* 1994;19:1307–1309.
- Hagberg M, Wegman DH. Prevalence rates and odds ratios of shoulder-neck diseases in different occupational groups. *Br J Ind Med* 1987;44:602–610.
- Westgaard RH, Jenssen C, Hansen K. Individualized work-related risk factors associated with symptoms of musculoskeletal complaints. *Int Arch Occup Environ Health* 1993;64:405–413.
- Daffner SD, Hilibrand AS, Anscom BS, Brislín BT, Vaccaro AR, Albert TJ. Impact of neck and arm pain on overall health status. *Spine* 2003;28:2030–2035.
- Takala EP, Viikari-Juntura E, Moneta GB, Saarenmaa K, Kaivento K. Seasonal variation in neck and shoulder symptoms. *Scand J Work Environ Health* 1992;18:257–261.
- Bergmann TF. Chiropractic technique. In: Gatterman MI, ed. *Foundations of Chiropractic: Subluxation*. 2nd ed. St. Louis, MO: Elsevier Mosby, 2005.
- Hooper PD. Evolution and basic principles of the chiropractic manipulation and adjustment. In: Haldeman S, Dagenais S, eds. *Principles and Practice of Chiropractic*. 3rd ed. New York: McGraw Hill, 2005.
- Grieve G. *Mobilization of the Spine*. New York: Churchill Livingstone, 1984.
- Gross AR, Kay TM, Kennedy C, et al. Clinical practice guideline on the use of manipulation or mobilization in the treatment of adults with mechanical neck disorders. *Man Ther* 2002;7:193–205.
- Philadelphia Panel Evidence-Based Clinical Practice Guidelines on Selected Rehabilitation Interventions for Neck Pain. *Phys Ther* 2001;81:1701–1717.
- Bronfort G, Haas M, Evans RL, Bouter LM. Efficacy of spinal manipulation and mobilization for low back pain and neck pain: A systematic review and best evidence synthesis. *Spine J* 2004;4:335–356.
- Coulter IA. Efficacy and risks of chiropractic manipulation: What does the evidence suggest? *Integ Med* 1998;1:61–66.
- DiFabio RP. The efficacy of manual therapy. *Phys Ther* 1992;72:853–864.
- Di Fabio RP. Manipulation of the cervical spine: Risks and benefits. *Phys Ther* 1999;79:50–65.
- Gross AR, Aker PD, Goldsmith CH, Peloso P. Conservative management of mechanical neck disorders: A systematic review and meta-analysis. *Online J Curr Clin Trials* 1996;5 (Doc. No. 200).
- Aker PD, Gross AR, Goldsmith CH, Peloso P. Conservative management of mechanical neck pain: A systematic overview and meta-analysis. *Br Med J* 1996;313:1291–1296.
- Gross AR, Aker PD, Quartly C. Manual therapy in the treatment of neck pain. *Rheum Dis Clin North Amer* 1996;22:579–598.
- Gross AR, Kay T, Hondras M, et al. Manual therapy for mechanical neck disorders: A systematic review. *Man Ther* 2002;131–149.
- Hoving JL, Gross AR, Gasner D, et al. A critical appraisal of review articles on the effectiveness of conservative treatment for neck pain. *Spine* 2001;26:196–205.
- Humphreys K. A review of the evidence of efficacy of cervical manipulation. In: Murphy DR, ed. *Conservative Management of Cervical Spine Syndromes*. New York: McGraw-Hill, 2000.
- Hurwitz EL, Aker PD, Adams AH, Meeker WC, Shekelle PG. Manipulation and mobilization of the cervical spine: A systematic review of the literature. *Spine* 1996;21:1746–1760.
- Kjellman GV, Skargren EI, Öberg BE. A critical analysis of randomized clinical trials on neck pain and treatment efficacy: A review of the literature. *Scand J Rehab Med* 1999;31:139–152.
- Koes BW, Assendelft WJJ, van der Heijden GJMG, Bouter L, Knipschild PG. Spinal manipulation and mobilization for back and neck pain: A blinded review. *Br Med J* 1991;303:1298–1303.
- Mior S. Manipulation and mobilization in the treatment of chronic pain. *Clin J Pain* 2001;17:S70–S76.
- Powell FC, Hanigan WC, Olivero MD. A risk/benefit analysis of spinal manipulation therapy for relief of lumbar or cervical pain. *Neurosurg* 1993;33:73–79.
- Salmi LR. Effectiveness of common treatments for neck pain. *Eur J Chiropr* 2002;49:40–46.
- Shekelle PG, Coulter I. Cervical spinal manipulation: A summary report of a systematic review of the literature and a multi-disciplinary expert panel. *J Spinal Dis* 1997;10:223–228.
- van Tulder MW, Goossens M, Hoving J. Nonsurgical treatment of chronic neck pain. In: Nachemson A, Jonsson E, eds. *Neck and Back Pain: The Scientific Evidence of Causes, Diagnosis and Treatment*. Philadelphia, PA: Lippincott Williams & Wilkins, 2000.
- Gross AR, Hoving JL, Haines TA, et al. Cervical Overview Group: A Cochrane Review of manipulation and mobilization for mechanical neck disorders. *Spine* 2004;29:1541–1548.
- Gross AR, Hoving JL, Haines TA, et al. Cervical Overview Group. Manipulation and mobilization for mechanical neck disorders. *Cochrane Database of Systematic Reviews* 2006; Issue 3.

38. Gross AR, Hoving JL, Haines TA, et al. Manipulation and mobilization for mechanical neck disorders. *Cochrane Library*, 2007, Issue 2.
39. CCA Guidelines Development Committee, et al. Chiropractic clinical practice guideline: Evidence-based treatment of adult neck pain not due to whiplash. *J Can Chiropr Assoc* 2005;49:158–209.
40. Vernon H, Humphreys BK, Hagino C. Chronic mechanical neck pain in adults treated with manual therapy: A systematic review of change scores in randomized clinical trials. *J Manipulative Physiol Ther* 2007;30:215–227.
41. Tseng YL, Wang WTJ, Chen WY, Hou TJ, Chen TC, Lieu FK. Predictors for the immediate responders to cervical manipulation in patients with neck pain. *Man Ther* 2006;11:306–315.
42. Tuttle N. Do changes within a manual therapy treatment session predict between-session changes for patients with cervical spine pain? *Aust J Physiother* 2005;51:43–48.
43. Tuttle N, Laakso L, Barrett R. Change in impairments in the first two treatments predicts outcome in impairments, but not activity limitations in sub-acute neck pain: An observational study. *Aust J Physiother* 2006;52:281–285.
44. Task Force on Taxonomy. *Classification of Chronic Pain: Descriptions of Chronic Pain Syndromes and Definitions of Terms*. 2nd ed. Merskey H, Bogduk N, eds. Seattle, WA: IASP Press, 1994.
45. Sherrington C, Herbert RD, Maher CG, Moseley AM. PEDro: A database of randomized trials and systematic reviews in physiotherapy. *Man Ther* 2000;5:223–226.
46. Maher CG, Sherrington C, Herbert RD, Moseley AM, Elkins M. Reliability of the PEDro Scale for rating quality of randomized controlled trials. *Phys Ther* 2003;83:713–721.
47. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. 2nd ed.. New York: Academic Press, 1988.
48. Ottenbacher KJ, Barrett K. Measures of effect size in the reporting of rehabilitation research. *Amer J Phys Med Rehabil* 1989;68:52–58.
49. Hanten WP, Barrett M, Gillespie-Plesko M, Jump K, Olson SL. Effects of active head retraction with retraction/extension and occipital release on the pressure pain threshold of cervical and scapular trigger points. *Phys Theory Pract* 1997;13:285–291.
50. Cassidy JD, Lopes AA, Yong-Hing K. The immediate effect of manipulation versus mobilization on pain and range of motion in the cervical spine: A randomized controlled trial. *J Manipulative Physiol Ther* 1992;15: 570–575.
51. Yurkiw D, Mior S. Comparison of two chiropractic techniques on pain and lateral flexion in neck pain patients: A pilot study. *Chiropr Tech* 1996;8:155–162.
52. Martinez-Segura R, Fernandez-de-las-Penas C, Ruiz-Saez M, Lopez-Jimenez C, Rodriguez-Blanco C. Immediate effects on neck pain and active range of motion after a single cervical high-velocity, low-amplitude manipulation in subjects presenting with mechanical neck pain: A randomized controlled study. *J Manipulative Physiol Ther* 2006;29:511–517.
53. Haas M, Group E, Panzer D, Partna L, Lumsden S, Aickin M. Efficacy of cervical endplay assessment as an indicator for spinal manipulation. *Spine* 2003;28:1091–1096.
54. Sloop PR, Smith DS, Goldenberg E, Dore C. Manipulation for chronic neck pain: A double-blind controlled study. *Spine* 1982;7: 532–535.
55. Vernon HT, Aker P, Burns S, Viljakaenen S, Short L. Pressure pain threshold evaluation of the effect of spinal manipulation in the treatment of chronic neck pain: A pilot study. *J Manipulative Physiol Ther* 1990; 13:13–16.
56. Sterling M, Jull G, Wright A. Cervical mobilisation: Concurrent effects on pain, sympathetic nervous system activity and motor activity. *Man Ther* 2001;6:72–81.
57. Hou CR, Tsai LC, Cheng KF, Chung KC, Hong CZ. Immediate effects of various physical therapy modalities on cervical myofascial pain and trigger point sensitivity. *Arch Phys Med Rehabil* 2002;83:1406–1414.
58. Howe DH, Newcombe RG, Wade MT. Manipulation of the cervical spine: A pilot study. *J R Coll Gen Pract* 1983;33:574–579.
59. Farrar JT, Young JP, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain* 2001; 149–158.
60. Vernon H, Humphreys BK, Hagino C. The outcome of control groups in clinical trials of conservative treatments for chronic mechanical neck pain: A systematic review. *BMC Musculoskel Dis* 2006;7:58.
61. Bird SB, Dickson EW. Clinically significant changes in pain along the Visual Analog Scale. *Ann Emerg Med* 2001;38:639–643.